VIRGINIA BOARD OF PHARMACY MINUTES OF BOARD MEETING

December 3, 2002 Department of Health Professions
Fifth Floor 6603 West Broad Street
Conference Room 2 Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:07

a.m.

PRESIDING: Carthan F. (Sonny) Currin, Jr., Board Chairman

MEMBERS PRESENT: Michael J. Ayotte

Willie Brown

Michelle R. Easton

Bobby Ison Leo H. Ross John G. Selph Jackson T. Ward

MEMBERS ABSENT: Mark A. Szalwinski

STAFF PRESENT: Elizabeth Scott Russell, Executive Director

Ralph A. Orr, Deputy Executive Director

Cathy M. Reiniers-Day, Deputy Executive Director Heather L. Womack, Administrative Assistant Elaine J. Yeatts, Senior Regulatory Analyst Howard M. Casway, Assistant Attorney General

QUORUM: With eight members of the Board present, a quorum was

established.

Mark Oley arrived at 9:15 a.m.

APPROVAL OF AGENDA: Mr. Ayotte moved, and the agenda was approved as amended to

include a request from the Virginia Dental Association for the

Board to review a legislative proposal.

PUBLIC COMMENTS: No public comments were received at this time.

APPROVAL OF MINUTES: Mr. Currin called for changes or corrections to the minutes of

September 30, 2002. The minutes were approved as presented.

ADOPTION OF RESPONSE TO PUBLIC COMMENT AND FINAL REGULATIONS FOR PHARMACY TECHNICIANS: The Board reviewed public comments concerning pharmacy technicians. Mr. Ayotte moved to amend the draft response to Mr. Belcher by striking the draft language, "Additionally, drug testing is not required for applicants for a pharmacist license, and pharmacists have much more independent access to a drug inventory than pharmacy technicians." After discussion and advice from counsel, Mr. Ayotte amended his motion to have the draft response state that the statute makes no provision for drug testing of pharmacy technicians, that drug testing is not a requirement for any applicant for a license from any Board within the Department of Health Professions, and that drug testing may be required by employers as a condition of employment. Mr. Ayotte further moved that the requirement for retesting a pharmacy technician whose registration has lapsed, remain at five years. He stated that much consideration has been given to the matter during the rulemaking process and that the Board had determined that after being out of practice for five years, knowledge and skills may need to be completely updated, but that for less than five years, evidence of continuing education should be sufficient for reinstatement. After consideration and discussion, the Board voted unanimously to accept the draft response to Mr. Belcher as amended. Alexander Macaulay representing Epic Pharmacies, on the comment by John Sisto, Medco Health stated that he felt the draft response did not completely address the comment. comment was amended to include language relating to the requirement for site-specific training. Mr. Ayotte moved, and the Board voted unanimously to accept the draft responses as proposed by staff and amended by the Board. (Attachment 1)

Mr. Selph moved, and the Board voted unanimously to adopt as final regulations the proposed regulations for pharmacy technicians without amendment. (Attachment 2)

REQUEST FOR
GUIDANCE CONCERNING
SECURITY
REQUIREMENTS FOR
NONCONTIGUOUS
AREAS FOR DRUG
STORAGE:

Samuel Johnson, Deputy Director of the Enforcement Division, requested guidance from the Board concerning the security requirements for non-contiguous areas of drug storage in pharmacies. The Board agreed that noncontiguous storage areas for drugs are part of the "prescription department" according to regulations, and, as such, have the same security requirements as the main part of the prescription department. If the pharmacy is open and staffed 24 hours a day, then an alarm is not required. However, if the pharmacy is not open 24 hours, then an alarm would be required for both the main prescription department and non-contiguous storage area(s).

REQUEST FOR GUIDANCE ON PHARMACY ENCLOSURE CONCERNING GATE SECURITY:

REQUEST FROM KINDRED HOSPITAL GREENSBORO CONCERNING OUT-OF-STATE REVIEW OF IN-STATE HOSPITAL ORDERS:

DRAFT LEGISLATION FOR DENTAL HYGIENTISTS:

The Board discussed a request for guidance on pharmacy enclosures concerning gate security. Mr. Johnson stated that during an inspection, the inspectors will cite a pharmacy if a proper locking device is not on the "swing" or "day" gate to prevent unauthorized access to the prescription department. The question_is whether or not a pharmacy needs a lock on the gate if a security grid or pull down cage is available to enclose the entire prescription department when the pharmacy is closed. After much discussion and upon advice from counsel, the Board reached consensus that the gate or door used to enclose the pharmacy during the day must have a proper locking device in order to meet the requirements of 18 VAC 110-20-190(1), (2), and (4).

Ms. Russell discussed with the Board a request from Kindred Hospital Greensboro. The Joint Commission on Accreditation of Healthcare Organizations has developed a standard that requires a pharmacist review all non-emergency/non pain medication orders before administration to a patient in a hospital or long term care facility. Kindred Healthcare wants to utilize a system where a pharmacist at a remote site, in this case in another state, reviews the order for appropriateness, checking the electronic medical record, reviewing for drug allergies, appropriate dosing and drugdrug interactions. The pharmacist may then give initial approval to start a medication and remove it from a night cabinet or an automated dispensing device. Kindred's question is whether the pharmacists performing this service must be licensed in Virginia. After discussion, the Board determined that if the remote pharmacists are performing functions for a Virginia pharmacy required to be performed by pharmacists, they would need to be licensed in Virginia.

At the request of the Virginia Dental Association (VDA), the Board reviewed draft legislation allowing dental hygienists to possess and administer certain Schedule VI topical drugs. Mr. Ward moved, and the Board voted unanimously to advise VDA that it was not opposed to the draft legislation provided the term "local" does not mean by injection and preferably is changed for clarification, and provided the phrase "in regulation" is added to the proposal after "approved by the Board of Dentistry."

EXECUTIVE DIRECTOR'S REPORT:

Ms. Russell reviewed with the Board upcoming National Association of Boards of Pharmacy (NABP) events. A training seminar concerning new options available for opioid addiction treatment is being conducted in Arlington, Virginia on January 10, 2003. A designated member of Board staff and a member of the

Board are invited to attend. Mr. Currin designated Mr. Ison and Ms. Russell to represent the Board.

Ms. Russell discussed with the Board that NABP is requesting comments and suggestions for the revision of NABP's constitution and bylaws. Ms. Russell requested that the Board email their comments to her by December 17, 2002 for submission, as final comments to NABP must be received by December 20, 2002.

REVIEW OF DISCIPLINARY ACTIONS:

The Board reviewed the list of disciplinary actions for August 2002 through November 2002. (Attachment 3)

APPROVAL OF CONSENT ORDER (S):

• CLOSED SESSION:

Mr. Ayotte moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A) (15) of the Code of Virginia for the purpose of deliberation to reach a decision on a consent order. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Ralph Orr, Howard Casway and Heather Womack attend the closed session because their presence is deemed necessary and will aid the Board in its deliberations.

• RECONVENE:

Mr. Ayotte moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

• **CONCLUSION:**

Board counsel advised that a consent order and Board ratification were not necessary in the matter of David W. Carter and directed staff to issue an order for the decision of the October 20, 2002 special conference committee.

ADJOURN:

With all business concluded, the meeting adjourned at 12:00 p.m.

Heather L. Womack
Administrative Assistant

Elizabeth Scott Russell
Executive Director

Carthan F. (Sonny) Currin, Jr., Board Chair

SUMMARY OF COMMENTS ON PROPOSED REGULATIONS

Virginia Board of Pharmacy

Regulations Governing the Practice of Pharmacy 18 VAC 110-20-10 et seq.

Pharmacy Technician Registration

Proposed regulations were published in the Virginia Register of Regulations on September 9, 2002. Public comment was requested for a 60-day period ending November 8, 2002. The following written comment was received:

John Sisto, representing Medco Health, commented on the requirement that technicians pass a test with recognized standards and administered by a third party. He argues that the only test that currently meets those requirements is the examination of the Pharmacy Technician Certification Board, which is a "relatively difficult examination." He requests a more practical method of testing the skills of technicians.

Draft Response:

The Board is in the process of developing an examination which will meet this criteria and only test the core competencies necessary for pharmacy technicians to perform the tasks set forth in the statute. It is planned that this examination will be administered to a large number of candidates the first year, and thereafter administered at least monthly at a minimum of three sites. There is also a provision for the board to approve other equivalent examinations, provided the examination meets the requirements of regulations. In addition, each pharmacy will be required to provide site-specific training for registered technicians.

Nathaniel Belcher, an interested citizen in Northern Virginia suggested that: 1) pharmacy technicians be required to provide current results of a certified drug test prior to application, examination or renewal and that such a test be the first step in any inquiry or investigation in which a technician is involved; 2) the pronouns "his" and "he be replaced with "their" and "they"; and 3) the requirement for a person to be retested who has allowed his registration to lapse for five or more years be changed to require retesting after a lapse of nine months or two years.

Draft Response:

- 1) The statute does not provide for drug testing prior to or as a part of applying for registration as a pharmacy technician. Drug testing may be a requirement for employment, but it is not required for any applicants for a health profession license.
- 2) The terms "he" and "his" are grammatically and legally correct and refer to either gender of applicant.
- 3) The Board considered the comment and determined that it was appropriate to require retraining and testing after five years rather than after a shorter period of time.

Such a requirement is necessary if someone has been out of the pharmacy for a period of time and needs to completely refresh and update his knowledge and skills. Reinstatement of a lapsed license within the five-year period will necessitate evidence of continuing education.

A Public Hearing before the Board was held on September 30, 2002, at which time there was comment from one person on the proposed rules for registration of pharmacy technicians.

Tom Stallings, representing the Virginia Association of Chain Drug Stores, supported the proposed regulations, which represent a significant amount of work and a "good-faith effort to balance and accommodate all the various and sometimes disparate views that were expressed". Therefore, his organization urges adoption of regulations in the current form without further modification.

Draft Response:

The Board appreciates Mr. Stallings comment and has not made further modification to the proposed regulations.

The Administrative Process Act requires that a summary of comment be sent to all commenters at least five days prior to the adoption of a final regulation. The Board will consider and respond to the comments prior to adoption of a final regulation on December 3, 2002.